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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,395	07/24/2000	Keiko Neriishi	Q58690	6421

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

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15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/624,395	NERIISHI, KEIKO	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *11* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 November 2002 has been entered.

2. This action is in response to papers filed 12 November 2002 in Paper No. 14 in which claims 7-9, 11-14, 16-17 and 20 were amended. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 7 dated 9 May 2002 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 7-20 are under prosecution.

Specification

3. The amendment filed 12 November 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claims 7, 8, 11-14, 16 and 17 have been amended to recite "known configuration". However, the specification as originally filed does not support the newly added limitation. Applicant points to pages 10 and 16 for support for

the limitation. The passage on page 10 teaches "biomolecules or ....detecting bodies may be arrayed in a matrix-like form in two-dimensional directions on the stimulable phosphor sheet" and the passage on page 16 teaches "previously stored information, which represents which cDNA is located at which site on the sitmulable phosphor sheet". The above teachings do to support the newly claimed "known configuration" which encompasses three-dimensional characteristics of the biomolecule and three-dimensional characteristics of the array of biomolecules not supported by the above teachings. As such, the newly added limitation introduces new matter into the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7, 8, 11-14, 16 and 17 (from which all other pending claims depend) have been amended to recite "known configuration". However, the specification as originally filed does not support the newly added limitation. Applicant points to pages 10 and 16 for support for the limitation. The passage on page 10 teaches "biomolecules or ....detecting bodies may be arrayed in a matrix-like form in two-dimensional directions on the stimulable phosphor sheet"

and the passage on page 16 teaches "previously stored information, which represents which cDNA is located at which site on the situmlable phosphor sheet". The above teachings do to support the newly claimed "known configuration" which encompasses three-dimensional characteristics of the biomolecule and three-dimensional characteristics of the array of biomolecules not supported by the above teachings. As such, the newly added limitation introduces new matter into the specification.

During an interview with Mr. Hissong on 8 November 2002, the phrase "predetermined configuration" was discussed as described in the attached Interview Summary. During the interview the examiner stated that "predetermined configuration" was not supported by the specification. The examiner further stated that the specification on page 16 does teach the information representing the site at which cDNAs are located is "previously stored". However, this teaching does not support the newly claimed "known configuration". It is suggested that the claims be amended to define the location of the biomolecules as described in the specification e.g. "wherein which biomolecule is located at which site on the array is known."

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 7, 8, 10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986). The claims are drawn to a microarray comprising a stimulable phosphor sheet and multiple kinds of biomolecules arrayed and fixed on the phosphor sheet in a known configuration. The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and the specification wherein it is unclear how the biomolecules are affixed on or within the phosphor layer wherein the microarray is defined as having "broad meanings embracing.... a macro array" (page 1, lines 14-16).

Regarding Claim 7, Shiraishi et al. disclose a microarray comprising a stimulable phosphor layer on a substrate wherein said phosphor layer has affixed thereto an array of biomolecules (Column 5, lines 53-65 and Column 13, lines 26-35) and wherein the biomolecules are in a known configuration (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Regarding Claim 8, Shiraishi et al. disclose a microarray comprising a stimulable phosphor layer on a substrate and a protective layer on the phosphor layer wherein the protective layer has affixed thereto an array of biomolecules (Column 12, line 67-Column 13, line 10) and wherein the biomolecules are in a known configuration (i.e. location information

indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Regarding Claim 10, Shiraishi et al. disclose the microarray wherein the biomolecule is an oligonucleotide (Column 13, lines 26-30).

Regarding Claim 13, Shiraishi et al. disclose a microarray comprising a stimulable phosphor layer on a substrate wherein said phosphor layer has affixed thereto an array of detecting bodies (Column 5, lines 53-65 and Column 13, lines 26-35) and wherein the biomolecules are in a known configuration (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Regarding Claim 14, Shiraishi et al. disclose a microarray comprising a stimulable phosphor layer on a substrate and a protective layer on the phosphor layer wherein the protective layer has affixed thereto an array of detecting bodies (Column 12, line 67-Column 13, line 10) and wherein the biomolecules are in a known configuration (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Regarding Claim 15, Shiraishi et al. disclose the microarrays of Claims 7, 8, 13 and 14 wherein the substrate is polyester (Column 7, lines 36-41).

Response to Arguments

8. Applicant comments on page 7 of the response that the instant claims are drawn to biomolecules and/or detecting bodies "directly contacting the phosphor layer or protective layer". Applicant points to pages 16 and 17 wherein the specification teaches that the molecules are fixed on the surface of the protective layer or within the protective layer. While the specification teaches the molecules are fixed on the surface of the protective layer or within the protective layer as cited, the specification and especially the portions cited do not provide support for the recitation biomolecules and/or detecting bodies directly contacting the phosphor layer or protective layer as asserted by Applicant. However, the comments are not relevant to the instant claims because the claims are not drawn to biomolecule and/or detecting bodies directly contacting the phosphor or protective layer.

Applicant further comments regarding the newly added limitation "known configuration" and points to pages 10 and 16 for support for the limitation. However, as discussed above, the phrase "known configuration" is not supported by the cited passages.

Applicant argues that because Shiraishi states that the support medium can be used for separation and identification of samples in autoradiograph and because their support medium is different from a protective layer on the phosphor sheet the teachings of Shiraishi in which an electrophoretic gel is placed on a stimulable phosphor sheet is clearly different from the instant invention in which the molecules are affixed on or within a phosphor layer. The argument has been considered but is not found persuasive because the claims are drawn to an array wherein affixed on (or within) a phosphor layer is an array of biomolecules. Shiraishi teaches an array comprising a stimulable phosphor layer wherein affixed on the phosphor layer via an electrophoretic gel is an array of biomolecule as claimed (Column 5, lines 59-65). The fact that Shiraishi uses their support medium for separation and identification does not alter the fact that they teach the array as claimed. It is noted that Shiraishi does not teach the biomolecules are affixed within the phosphor layer. However, the claims are drawn in the alternative to being affixed on or within the phosphor layer. Because Shiraishi teaches affixed on the phosphor layer, they teach the array as claimed.

Applicant states that the identify and location of each biomolecule or detecting body is known prior to the use of the microarray. In contrast, Applicant argues, the identity and location of biomolecules on the array of Shiraishi would not be known prior to hybridization with a labeled probe. The argument has been considered but is not found persuasive because the argument does not address limitations of the claims. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). The claims are drawn to an array comprising a stimulable phosphor layer provided on a substrate wherein affixed on (or within) the phosphor layer is an array of a biomolecule in a known configuration. As stated above, Shiraishi teaches the array as claimed. The open claim language "comprising" encompasses the additional elements e.g. labeled probes.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 11, 12 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986) in view of Davis et al. (Basic Methods in Molecular Biology, "DNA Hybridization", 1986, pages 84-87).

Regarding Claims 11, 12, 16 and 17, Shiraishi et al. teach a method for analyzing a biomolecule (Claims 11 & 12) and a sample (Claims 16 & 17) comprising: preparing a microarray comprising a stimulable phosphor layer and/or the protective layer wherein the stimulable phosphor layer has arrayed and affixed thereto an array of biomolecules/detecting bodies (i.e. labeled molecules e.g. proteins and nucleic acids); causing the stimulable phosphor sheet to store energy from the energy generating substance with which the fixed biomolecule is labeled; exposing the stimulable phosphor sheet to stimulating rays which cause the phosphor sheet to emit light in proportion to the amount of energy stored thereon and photoelectrically detecting the emitted light to detect the labeled biomolecule (Column 13, line 41-Column 14, line 5 and Column 14, line 49-Column 15, line 32) and wherein the biomolecules are in a known configuration (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed.

Shiraishi et al. teach the biomolecule is labeled and they teach providing the label by known methods (Column 13, lines 26-40) but they do not specifically teach labeling the fixed biomolecule by hybridization with a labeled biomolecule. However, labeling a biomolecule by hybridization with a labeled biomolecule was well known in the art at the time the claimed invention was made as taught by Davis et al. Specifically, Davis et al. teach hybridizing a labeled biomolecule with a biomolecule fixed on a support (page 85). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the labeling of Shiraishi et al. wherein all of the arrayed and fixed biomolecules are radioactively labeled with the labeling taught by Davis et al. wherein only biomolecular probes are labeled and wherein the labeled probes hybridize to specific arrayed biomolecules to thereby detect only specific biomolecule(s) and based on the known hazards of radioactive labels, label biomolecular-specific probes and hybridizing the probes to the arrayed biomolecules thereby reducing the number of radio-labeled biomolecules and reducing non-specific detection for the expected benefit of reduced biohazard risk and increased biomolecule-specific detection.

Regarding Claim 18, Shiraishi et al. the methods of Claims 11, 12, 16 and 17 wherein the substrate is polyester (Column 7, lines 36-41).

Regarding Claim 19, Shiraishi et al. teach the methods of Claims 11 and 12 wherein the biomolecule is an oligonucleotide (Column 13, lines 26-30).

Response to Arguments

11. Applicant comments on page 11, that in view of the previous comments and the amendments, Shiraishi does not render obvious the claims. Applicant further asserts that Davis et al do not teach or suggest fixation or within the phosphor layer. The arguments have been considered but are not found persuasive for the reasons stated above.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986) in view of Heller et al (U.S. Patent No. 5,632,957, issued 27 May 1997).

Regarding Claim 9, Shiraishi et al a microarray comprising a stimulable phosphor layer on a substrate and a protective layer on the phosphor layer wherein the protective layer has affixed thereto an array of biomolecules (Column 12, line 67-Column 13, line 10) wherein the biomolecules are in a known configuration (i.e. location information indicating the shape and position of the biomolecules is obtained (Column 16, lines 25-33) thereby obtaining the array as claimed. Shiraishi et al further teach the microarray wherein the protective layer comprises polyacrylamide (Column 12, lines 13-20) and the biomolecules are affixed by electrophoretic resolution using "well known" methods (Column 13, lines 36-40) but they do not specifically teach the protective layer comprises poly-l-lysine. However, electrophoretic resolution on polyacrylamide comprising poly-l-lysine was well known in the art at the time the claimed invention was made as taught by Heller et al (Column 17, lines 54-65). Specifically, Heller et al teach a similar microarray comprising biomolecules arrayed and affixed to a polyacrylamide protective layer (Column 5, lines 3-8) wherein the surface of the polyacrylamide is functionalized with poly-l-lysine to thereby provide for covalent attachment of biomolecules to the surface (Column 18, lines 5-10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the surface modification taught by Heller et al to the polyacrylamide surface of Shiraishi et al to thereby provide for covalent attachment of the biomolecules. One skilled in the art would have been motivated to covalently attach the biomolecules of Shiraishi et al to thereby provide stable, specific and localized biomolecule binding for the expected benefit facilitating detection and analysis of the biomolecule and its interactions.

Response to Arguments

13. Applicant reiterates the arguments regarding Shiraishi and further asserts that Heller et al do not teach or suggest fixation or within the phosphor layer. The arguments have been considered but are not found persuasive for the reasons stated above.

14. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986) in view of Davis et al. (Basic Methods in Molecular Biology, "DNA Hybridization", 1986, pages 84-87) as applied to Claim 12 above and further in view of Heller et al (U.S. Patent No. 5,632,957, issued 27 May 1997).

Regarding Claim 20, Shiraishi et al. teach a method for analyzing a biomolecule (Claims 11 & 12) and a sample (Claims 16 & 17) comprising: preparing a microarray comprising a stimulable phosphor layer and/or the protective layer wherein the stimulable phosphor layer has arrayed and affixed thereto an array of biomolecules/detecting bodies (i.e. labeled molecules e.g. proteins and nucleic acids); causing the stimulable phosphor sheet to store energy from the energy generating substance with which the fixed biomolecule is labeled; exposing the stimulable phosphor sheet to stimulating rays which cause the phosphor sheet to emit light in proportion to the amount of energy stored thereon and photoelectrically detecting the emitted light to detect the labeled biomolecule (Column 13, line 41-Column 14, line 5 and Column 14, line 49-Column 15, line 32) wherein the protective layer comprises polyacrylamide (Column 12, lines 13-20) and the biomolecules are affixed by electrophoretic resolution using "well known" methods (Column 13, lines 36-40) but they do not specifically teach the protective layer comprises poly-l-lysine. However, electrophoretic resolution on polyacrylamide comprising poly-l-lysine was well known in the art at the time the claimed invention was made as taught by Heller et al (Column 17, lines 54-65). Specifically, Heller et al teach a similar

method wherein biomolecules arrayed and affixed to a polyacrylamide protective layer (Column 5, lines 3-8) wherein the surface of the polyacrylamide is functionalized with poly-l-lysine to thereby provide for covalent attachment of biomolecules to the surface (Column 18, lines 5-10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the surface modification taught by Heller et al to the polyacrylamide surface of Shiraishi et al to thereby provide for covalent attachment of the biomolecules. One skilled in the art would have been motivated to covalently attach the biomolecules of Shiraishi et al to thereby provide stable, specific and localized biomolecule binding for the expected benefit facilitating detection and analysis of the biomolecule and its interactions. Shiraishi et al. teach the biomolecule is labeled and they teach providing the label by known methods (Column 13, lines 26-40) but they do not specifically teach labeling the fixed biomolecule by hybridization with a labeled biomolecule. However, labeling a biomolecule by hybridization with a labeled biomolecule was well known in the art at the time the claimed invention was made as taught by Davis et al. Specifically, Davis et al. teach hybridizing a labeled biomolecule with a biomolecule fixed on a support (page 85).

Response to Arguments

15. Applicant comments on page 13, that in view of the previous comments and the amendments, Shiraishi does not render obvious the claims. Applicant further argues that Shiraishi et al in view of Davis et al and Heller et al render the obvious the invention of Claim 20. The arguments have been considered but are not found persuasive for the reasons stated above.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
January 21, 2003